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EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

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DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/674,034

Applicant(s)

SAVOLAINEN, JOUKO

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.                      6) ☐ Other: \_\_\_\_\_

Art Unit: 1653

### **DETAILED ACTION**

#### **ACKNOWLEDGMENT FOR PRIORITY, PRELIMINARY AMENDMENT, IDS, STATUS OF THE APPLICATION AND CLAIMS**

1. This application is filed under 35 U.S.C. 371 on 1/3/01 having a filing date of 4/28/99 of PCT/F99/00347. Acknowledgment is made of Applicant's claim for priority based on Finnish application number 980945 having a filing date of 4/29/98. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The Information Disclosure Statement (IDS) and Form PTO-1449 and the preliminary amendment filed 1/3/01 are acknowledged, entered and considered. In view of Applicant's request claims 5 and 6 have been amended. Thus, claims 1-12 are now pending.

#### **OBJECTION TO THE SPECIFICATION**

2. The specification is objected because there are no Headings disclosed in the disclosure. It is also noted that the conventional practice of USPTO requires that numbers having decimals should be identified in dots (.) or full stops (.) and not in commas (,) as currently disclosed in the instant specification (See e.g., page 4, line 31, in the recitation "2,1 liters, 0,5 M Tris buffer, pH 8,5, with 4,78 g Na<sub>2</sub>SO<sub>3</sub>, etc.,). Thus, it is suggested according to USPO practice that Applicant amend the specification by changing (,) to--(.)-- wherever it occurs in identifying numbers having decimals. Also, on page 2, line 17, there appears to be typographical error in the recitation "hydrofobicity". Appropriate correction is required.

Art Unit: 1653

Further, the following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the Applicant's use.

### **ARRANGEMENT OF THE SPECIFICATION**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).

Art Unit: 1653

- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). Although, this application is filed under 371, but, providing an abstract on a separate sheet is suggested.

#### **CLAIM REJECTION-35 U.S.C. § 112, FIRST PARAGRAPH**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Modification and isolation step(s) is/are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Independent claim 1 and dependent claims thereof recite a method for modification and isolation of a protein....., however, the claims do not recite the essential process step(s) for achieving the result of modification and isolation of a protein. Thus, the critical step(s) necessary for achieving the invention should be included at least in independent claim 1.

Art Unit: 1653

**CLAIMS REJECTION-35 U.S.C. § 112<sup>2nd</sup> PARAGRAPH**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 is indefinite and incomplete in failing to recite method step(s) of a process for the modification and isolation of a protein such as whey or soy proteins. Although, claim 1 states “contact, forms sulfite ions, sulfonated, precipitated, recovered.....”, but, the claim does not use active method step(s) i.e., contacting, forming sulfite ions, sulfonating, precipitating, recovering.....ect., and it is not clear how the step(s) of modification and isolation of proteins, especially from whey or soy or concentrate thereof is brought in contact with a reagent that forms sulfite ions in order to sulfonate the proteins and thereby precipitated and recovered without active method step(s). There is/are no active method step(s) for contacting, forming sulfite ions, sulfonating, precipitating and recovering. Thus, use of active method step(s) would obviate this rejection.

Claim 1 is indefinite in the recitation “especially” because the term “especially” appears to be superfluous in the claim as it does not serve to define and/or limit the *method* claimed. Deletion of this term is suggested as it would not affect the scope of the claim.

Art Unit: 1653

Claims 1-12 are indefinite in the recitation “characterized” because the characterization of use can be recited by amending the claims to recite “wherein” or “comprising”, etc. Thus, it is suggested that the term “wherein” or “comprising”, etc. should be replaced in the recitation thereof.

Claims 1 and 10 are indefinite in the recitation “the sulfonated protein or the precipitated and/or soluble sulfonated protein” because they contain the use of an alternative expression wherein the limitation covers two elements, i.e., “precipitated sulfonated protein” is not the same as “soluble sulfonated protein” and vice versa.

Claims 1 and 10 are grammatically indefinite in the recitation “the sulfonated protein or the precipitated and/or soluble sulfonated protein. Although, two elements are intended (i.e., precipitated sulfonated protein and soluble sulfonated protein, See also claim 10, line 4 which states whereby both are liberated.....); but, the claims as drafted appears that there are three elements in the claims, namely, sulfonated protein, precipitated protein and soluble sulfonated protein. Appropriate correction is required.

There is also inconsistency between claims 1 and 10 because claim 1 recite “sulfonated protein” while claim 10 recite “sulfonated proteins”. Thus, appropriate correction is required.

Claim 1 is indefinite in the recitation “optionally” because if an ingredient, a step, or other structural element is truly optional, i.e., its presence is not necessary for attainment of the result that is an object of the invention, then recitation thereof does not belong in the claim.

Art Unit: 1653

Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 2 is indefinite and confusing in the recitation "a temperature of 40-65°C, preferred is 50-60°C" because the claim recites two different ranges in one claim. If Applicant intends to claim the preferred range as well as the broad range, then, the Office recommends the use of two dependent claims claiming the recited ranges.

Claim 3 recites the limitation "the protein content" in lines 1-2. There is insufficient antecedent basis for this limitation in claim 1 or claim 2 or claim 3.

Similarly claim 4 is indefinite and confusing in the recitation "a temperature of 60-80°C, preferred is 65-75°C" for the same reasons discussed under the rejection of claim 2 above.

Claim 5 is indefinite in the recitation "at (a) the pH is adjusted....." because there is no proper antecedent basis for the pH in (a), rather, pH is recited in (b). Appropriate correction is required.

Claim 5 is also indefinite and confusing in the recitation "the pH is adjusted to 5,5-8, preferred is 6-7" because the claim recites two different ranges in one claim. If Applicant intends to claim the preferred range as well as the broad range, then, the Office recommends the use of two dependent claims claiming the recited ranges.

The syntax of claim 6 is indefinite in the recitation "A method according to one claim 5". It appears that the phrase "to one" is superfluous. Deletion of this phrase is suggested.



Art Unit: 1653

Claims 5-6, 9-10 and 12 are indefinite in using commas (,) to identify decimal numbers. Amendment of the claims by changing the commas (,) to dots (.) (i.e., changing 0,05-0,10 M to 0.05-0.10 M) for identifying the decimal numbers would obviate this rejection.

Claim 6 recites the limitation "in stage (a)" in line 2. There is insufficient antecedent basis for this limitation in claim 1 or claim 2 or claim 5 or claim 6.

Claim 6 is indefinite and confusing in the recitation "a concentration of 0,02-0,20 M, preferred is 0,05-0,10 M" because the claim recites two different ranges in one claim. If Applicant intends to claim the preferred range as well as the broad range, then, the Office recommends the use of two dependent claims claiming the recited ranges.

Claim 7 recites the limitation "the sulfonation degree" in line 1. There is insufficient antecedent basis for this limitation in claim 1 or claim 7.

Claim 7 is indefinite and vague in the recitation "the sulfonation degree of the protein is affected by varying reaction conditions.....". It is not clear what the "varying" reaction conditions are. Appropriate clarification is required.

Similarly claim 9 is also indefinite and confusing in the recitation "lowering the pH to 1,5-5,5, preferred is 4,0-5,0" for the same reasons discussed under the rejection of claim 5 above.

Claim 10 recites the limitation "the sulfone groups" in lines 2-3. There is insufficient antecedent basis for this limitation in claim 1 or claim 10.

Claim 11 recites the limitation "the remaining sulfite" in lines 1-2. There is insufficient antecedent basis for this limitation in claim 1 or claim 10 or claim 11.

Art Unit: 1653

**CLAIMS REJECTION-35 U.S.C. § 103(a)**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/22907 taken with Petruccelli et al., (J. Agric. Food Chem., Vol. 43, pp. 2001-2006, 1995).

The instantly claimed invention is directed to a method for modification and isolation of proteins from whey or soy comprising a) a protein such as whey or soy or a concentrate thereof is brought into contact with a reagent that forms sulfite ions in order to sulfonate the protein without using an oxidizing agent, b) the sulfonated protein is precipitated at an acid pH, and c) the sulfonated protein or the precipitated and soluble sulfonated protein is recovered and optionally processed further.

Similarly, WO 95/22907 teaches a method for modification and isolation of protein from whey comprising a) whey or a concentrate thereof, a reagent which forms sulfite ions, and an oxidant are brought into contact in order to sulfonate, b) the sulfonated and oxidized whey protein is precipitated out from the whey or concentrate thereof at an acid pH, and c) the precipitated sulfonated and oxidized whey protein is recovered from the product mixture and possibly subjected to an after-treatment (See e.g., page 1 lines 4-14). The precipitation step b) preferably carried out by using a pH value of approximately 2.5-6.5, and most preferably a pH

Art Unit: 1653

value of 3.0-5.0. After the pH adjustment of step b), the temperature is adjusted to be sufficiently high, preferably within the range 25-55°C, most preferably within the range 30-50°C. The protein content of the whey concentrate is 2-7% and the dry weight of the concentrate is 11-12%. The sulfonation in a) employs the sulfite as  $\text{Na}_2\text{HSO}_3$ ,  $\text{Na}_2\text{SO}_5$  or  $\text{Na}_2\text{SO}_3$  and is used at the concentration in an amount of 0.02-0.20 M, preferably 0.05-0.1 M (See e.g., page 9, lines 30 to page 10, lines 8; page 11, lines 34 to page 12 lines 26; claims 1-2, 4 and 7-8).

The reference of WO 95/22907 differs from claims 1-12 in not teaching the sulfonation of the whey protein without using oxidizing agent (i.e., omitting the oxidation step in the claimed process). Although, on pages 5-6, the primary reference discloses the advantages and disadvantages of using oxidative sulfitolysis with the purpose of isolating proteins from whey wherein the oxidant being oxygen and the catalyst a  $\text{Cu}^{++}$  ion as  $\text{CuCO}_3$ . Based on oxidative sulfitolysis, the result either did not aim at providing a method of isolation but only a method of modifying certain properties, or the method is so difficult to exploit on an industrial scale that it cannot be implemented. Thus, the primary reference clearly suggests that the use of oxidizing agent would decrease the yield of the product desired in large scale production. Further, the secondary reference of Petruccelli et al., teach the partial reduction of disulfide bonds of soy protein isolates in which the addition of catalyst (Cu) and oxygen showed a similar effect in the sulfitolysis of soy proteins with  $\text{Na}_2\text{SO}_3$ . (See e.g. abstract). On page 2006, the reference clearly shows that in the presence of a catalyst (Cu) and/or an oxidizing agent ( $\text{O}_2$ ), the AB-11S subunits is not completely reduced, probably because the reducing agent is unable to reach all SS bonds.

Art Unit: 1653

Reduction of soy protein isolates with sodium sulfite affects different subunits according to the reaction conditions employed; namely, mostly AB dimers are reduced if urea is used, whereas if Cu or O<sub>2</sub> is employed, mainly components other than AB-11S undergo change. The reference continues by stating that to obtain complete sulfitolysis, both urea and C or O<sub>2</sub> are required. The reference concludes by stating that the addition of a catalyst (Cu) and oxidizing agent (O<sub>2</sub>) affects similarly the sulfitolysis of soy proteins with Na<sub>2</sub>SO<sub>3</sub>; the simultaneous presence of both agents is not required. Thus, clearly showing that without using an oxidizing agent that one of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy.

Therefore, the employment of a method for modification and isolation of a protein such as whey or soy protein by sulfonating the protein with or without using an oxidizing agent and then precipitating the sulfonated protein at acidic pH and recovering thereof in the manner claimed in claims 1-12 appears to be obvious as taught by the combined teachings of the prior art at the time the invention was made because the secondary reference clearly taught the simultaneous presence of both agents (i.e., catalyst and oxidizing agent) is not required. Hence, one of ordinary skill in the art would have been motivated to modify the method for modification and isolation of proteins from whey which requires oxidizing agent taught by the primary reference to substitute into a method for modification and isolation of proteins from whey without using oxidizing agent as taught or suggested by the secondary reference since the secondary reference has shown as discussed above that without using an oxidizing agent that one

Art Unit: 1653

of ordinary skill in the art would be able to obtain complete sulfitolysis in a method for modification and isolation of proteins from whey or soy. Thus, it would have been obvious to one of ordinary skill in the art to apply the teachings of the secondary reference to the primary reference because such features <sup>(sulfonating) Oxidizing</sup> are known and suggested in the art, as seen in the secondary reference, and including such features into the method of the primary reference would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

Therefore, in view of the above and in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated at the time the invention was made to employ a method for modification and isolation of a protein such as whey or soy protein by sulfonating the protein without using an oxidizing agent and then precipitating the sulfonated protein at acidic pH and recovering thereof in the manner claimed in claims 1-12; which fall within the scope of the combined teachings of the prior art method would have been prima facie obvious from said prior art disclosure to a person of ordinary skill in the art because in the absence of sufficient objective factual evidence or unexpected results to the contrary, Applicant's claims are directed to optimization of an "art recognized variable" which is well within the purview of one of ordinary skill in the art, In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Art Unit: 1653

### CONCLUSION AND FUTURE CORRESPONDENCE

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m.. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Abdel A. Mohamed*  
ABDEL MOHAMED  
PATENT EXAMINER  
GROUP 1800  
TC 1600

*AAM* Mohamed/AAM

January 24, 2003